DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-23AQ; Docket No. CDC-2022-0129]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP). This project is a prospective cohort study to understand men who have sex with men's (MSM) strategies to prevent HIV and sexually transmitted infections (STIs), including pre-exposure prophylaxis (PrEP) use and adherence, condom use, sexual risk-taking behavior and substance-using behaviors.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0129 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed

collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP) – New – National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) is requesting approval for 36 months of data collection entitled Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP). The purpose of this study is to enroll a prospective cohort of men who have sex with men (MSM) in Atlanta, Detroit, and San Diego to understand men's strategies to prevent HIV and other STIs including PrEP use and adherence, condom use, sexual risk-taking behavior, and substance-using behaviors. This study also proposes to assess men's use and preferences for prevention modalities and assess men's awareness, knowledge, beliefs, and perceptions about HIV/STI prevention products.

The information collected in this study will be used to: 1) describe real-world HIV and STI prevention strategies including PrEP use and adherence and condom use; 2) better understand men's use, preferences, knowledge, and perceptions about

prevention modalities; 3) develop rapid reports that will allow for summary recommendations concerning gaps in prevention protection; and 4) provide timely new information to public health programs and decision makers.

The study will be carried out in three cities, Atlanta, GA; Detroit, MI; and San Diego, CA. Participants will include 1275 HIV-negative men ages 18 and older. Participants will identify as cisgender male; report male at birth; report sex with a man in the last six months; live in or near Atlanta, Detroit, or San Diego; own a cell phone with data service; be willing to download a health-related app as part of the study; be able to provide two or more means of contact; be fluent in written/spoken English or Spanish; and not currently be enrolled in another HIV prevention clinical trial. We will use purposive sampling to ensure that 60% of participants will be PrEP users at baseline, and 40% will not be using PrEP. We will also oversample Black and Hispanic MSM to ensure that a minimum of 30% each are represented in the cohort sample. Participants will be recruited using a combination of approaches including social media, referral, and in-person outreach.

Quantitative and qualitative assessments will be used to collect information from participants. A quarterly quantitative survey will assess use of prevention modalities, awareness, knowledge, beliefs, and perceptions about HIV/STI prevention products and prevention messages. The SMaRT app study management platform allows for scheduling, reminders, survey

administration, and communication by email and text messaging. HIV and STI test results will allow the study team to assess HIV and STI risk throughout the study period. A subset of the participants will be invited to further participate in qualitative data collection activities including focus groups and in-depth interviews. The focus groups will assess the participants' awareness of PREP messages, preferences for PrEP messages, and perceived impact/efficacy of HIV prevention and PrEP messages. The in-depth interviews will assess men's PrEP experiences, their preferences for PrEP and other HIV prevention products, and further explore their reactions to prevention messages.

The screening process is estimated to take five minutes to complete. We estimate that the contact information gathering and the SMaRT app installation will take five minutes each to complete. The quantitative assessment is estimated to take 45 minutes to complete and will be delivered quarterly for a total eight times over the two-year follow up period. Participants will be asked to collect specimens for both HIV and STI testing at six-month intervals for a total of four times over the two-year follow up period. The specimen kit for HIV testing will take approximately 15 minutes to complete. The specimen kit for STI testing will take approximately 30 minutes to complete. A subset of the 1275 enrolled participants will be invited to participate in qualitative data activities: 270 participants will engage in a focus group that is estimated to take 90

minutes to complete, and 30 participants will be invited to participate in three in-depth interviews to be delivered at six-month intervals over the two-year follow up period. The interviews will take approximately 90 minutes to complete.

CDC requests OMB approval for an estimated 2,214 annual burden hours. There are no costs to the respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
General Public – Adults	Eligibility Screener	850	1	5/60	68
General Public - Adults	Contact Information	425	1	5/60	34
General Public - Adults	SMaRT App Installation	425	1	5/60	34
General Public - Adults	Quantitative Survey	425	4	45/60	1275
General Public - Adults	Sample Collection for HIV Test	425	2	15/60	213
General Public - Adults	Sample Collection for STI Test	425	2	30/60	425

General Public - Adults	Focus Group Guide	90	1	90/60	135
General Public - Adults	In-Depth interview Guide	10	2	90/60	30
Total					2214

Jeffrey M. Zirger,

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